

Insert address of local BD contact office

Insert customer name & address

URGENT: FIELD SAFETY NOTICE
Advisory Notice

BD Reference: FA_11_044_104

Date:

Subject: BD Venflon 22GA, 0.8 x 25mm, Peripheral IV Catheter

BD Product Ref#: 391451

BD Product Lot#: 10F2941E

For the Attention of ([Enter customer contact](#))

BD has become aware of a labelling anomaly concerning the single lot number identified above. This labelling anomaly is apparent on 320 shelf boxes representing 16,000 individual units from a total batch of 175,000 units, 3,500 shelf boxes.

All shipping cartons and individual unit packs are correctly labelled. The shipping cartons each contain 10 shelf boxes.

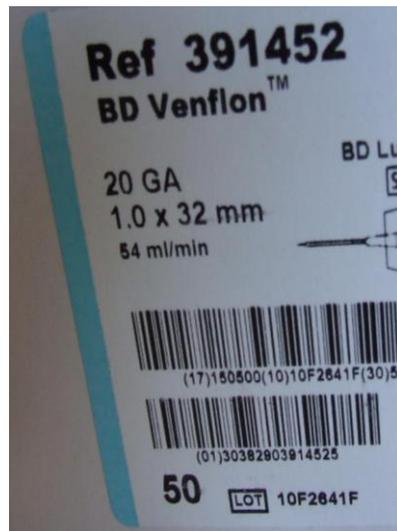
The **incorrectly labelled shelf boxes** carry the following information:

- The blue colour coding representing a 22GA catheter. The colour identification strip identifies the correct gauge size.
- A ref# of 391452 instead of ref# 391451
- A gauge of 20GA instead of 22GA.
- A catheter size of 1.0 x 32mm, instead of 0.8 x 25mm.
- A flow rate of 54 mL/min instead of 31 mL/min.
- A lot number of 10F2641F instead of lot number 10F2941E.

The **correct** shipping carton label, which provides the same correct information as the individual unit label is as below:



The **incorrect** shelf box label is as below:



What you need to do

To assist Becton Dickinson with this action, please be aware of the analysis supplied above and communicate the information within your organization. Based on a health risk assessment, BD is not requesting that your organization ceases to use the affected product. However if your organization requires the withdrawal of any affected products please contact the BD office identified below.

Please complete and return the attached **Response Card** to the local BD office identified in order to confirm receipt of this advisory notice.

Please forward this information immediately to all departments within your organisation who may be using, or ordering these products. Additionally, please ensure that a copy of this letter is provided to any other organisations to which the affected devices have been transferred.

Please accept our apologies for the inconvenience caused by this action.

If you have any questions regarding this communication, please contact the following telephone number **(BD office contact tel. number)**

Yours sincerely,

(Name & Signature of Local Contact)



CUSTOMER RESPONSE CARD for:

BD Venflon 22GA 0.8 x 25mm

Please complete by checking the appropriate box. Even if you have no inventory of listed product lots, please indicate this below and return this card by fax. If you currently have stock, complete the form noting quantity in units next to the lot number and return this card by fax.

- We acknowledge the receipt of the advisory notice
- We acknowledge the receipt of the advisory notice and we have the following stock that we will be returning **(Please list below)**

REF	LOT NUMBER	QUANTITY
391451	10F2941E	

Please fax to {Contact Name} at {Fax Number}.

If you have any questions concerning this, please contact {Name} @ {Contact Number} between {Time} am – {Time} pm, Monday – Friday.

Please do not return affected products without having made arrangements with your local BD Office.

_____	_____	_____	
Contact Name (please print)	Title	Signature and date	
_____	_____	_____	_____
Facility Name	Address	Phone Number	Fax Number